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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,017	01/05/2001	D. Wade Walke	LEX-0115-USA	4534

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/755,017	WALKE ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-9 are under consideration in the instant application.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

1. Claims 3-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for claims 1-8 at pages 2-14 of the previous Office Action (23 October 2003).

Specifically, the claims recite an isolated nucleic acid molecule comprising the nucleic acid sequence presented in SEQ ID NO: 1. The claims also recite an isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2. Additionally, the claims are directed to expression vectors and host cells comprising the nucleic acid molecules. Claim 9 is directed to an isolated nucleic acid molecule encodes SEQ ID NO: 2 and hybridizes under stringent conditions with wash conditions of 0.1xSSC/0.1% SDS at 68°C to the nucleotide sequence of SEQ ID NO: 1.

Applicant's arguments (23 August 2004), as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

(i) Applicant asserts that the Examiner is of the opinion that the various mandatory legal precedents provided in Federal Circuit decisions are narrowly limited to the particular

technologies discussed in each specific case. Applicant argues that the Examiner's position lacks any legal and procedural foundation and is intellectually unsound.

Applicant's arguments have been considered but are not found to be persuasive. Specifically, the issue is not what the technology is, rather, it is what aspect of the requirements of 35 USC § 101 is not met. In the fact pattern of the case law, the invention was inoperative. In the instant case, the fact pattern is significantly different: there is no question of operability. Rather, it is a question of whether or not the asserted utility is credible, specific and substantial.

(ii) Applicant contends that evidence has been previously presented indicating that the claimed sequences have been identified by third party scientists as human olfactory receptor 2B6 (Hs6M1-32). Applicant submits that those of skill in the art when faced with the same sequences as those claimed in the present application readily identified them as those encoding a G protein-coupled receptor. Applicant states that the assertions are credible and have been corroborated by an unaffiliated third party.

Applicant's arguments have been considered but are not found to be persuasive. As discussed in the previous Office Action, Ji et al. (J Biol Chem 273(28): 17299-17302, 1998) indicate that G protein coupled receptors are classified into over 100 subfamilies according to sequence homology, ligand structure, and receptor function. A substantial degree of amino acid homology is found among members of a particular subfamily, but comparisons between subfamilies show significantly less or no similarity. Mutant G protein coupled receptors are incapable of binding ligand or generating normal signals, constitutively generate signals, or are not appropriately expressed on the cell surface (pg 17299, pp 1-2). Also, "an increasing number

of G protein coupled receptor subfamilies show diverse modes of ligand binding, signal generation, transmembrane signal transduction, and signal transfer to various cytoplasmic signal molecules other than G protein" (pg 17302, pp 4). Furthermore, since the specification does not disclose any methods or working examples that demonstrate the NGPCR polynucleotide and polypeptide of the instant application exhibit similar activities of other G-protein coupled receptors, particularly odorant receptors, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application as a G-protein coupled receptor. Additionally, the specification of the instant application does not teach the skilled artisan which domains of the NGPCR polynucleotide and polypeptide are structurally characteristic of G protein-coupled receptors. One skilled in the art would not know the utility and function of NGPCR (SEQ ID NO: 2), even if it was a putative G protein coupled receptor because, as discussed in the related art above, G protein coupled receptors include a wide range of biologically active receptors, and neither the prior art nor the specification provides for the physiological significance of the disclosed and claimed receptor.

It is noted to Applicant that the specification of the instant application does not disclose that the claimed polynucleotide of SEQ ID NO: 1 or the polypeptide of SEQ ID NO: 2 are specifically homologous to *odorant/olfactory* receptors. Furthermore, the human olfactory receptor 2B6 (Hs6m1-32), which Applicant asserts the polypeptide of the instant application is 100% homologous to, has not been well characterized in the art as an odorant receptor. Since the human olfactory receptor 2B6 has no functional or structural characteristics described in the art, the polypeptide of SEQ ID NO: 2 of the instant application has no credible, specific and substantial asserted utility or a well established utility.

Furthermore, the assertion that the disclosed NGPCR polynucleotides and polypeptides have biological activities similar to known odorant/olfactory receptors cannot be accepted in the absence of supporting evidence, because the relevant literature reports examples of polypeptide families wherein individual members have distinct, and sometimes even opposite, biological activities. For example, Tischer et al. (U.S. Patent 5,194,596) establishes that VEGF (a member of the PDGF, or platelet-derived growth factor, family) is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells, which is opposite to the mitogenic activity of naturally occurring PDGF which is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (column 2, line 46 to column 3, line 2). The differences between PDGF and VEGF are also seen *in vivo*, wherein endothelial-pericyte associations in the eye are disrupted by intraocular administration of PDGF but accelerated by intraocular administration of VEGF (Benjamin et al., 1998, Development 125:1591-1598; see Abstract and pp. 1594-1596). In the transforming growth factor (TGF) family, Vukicevic et al. (1996, PNAS USA 93:9021-9026) disclose that OP-1, a member of the TGF-β family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF-β family members BMP-2 and TGF-β1 had no effect on metanephrogenesis under identical conditions (p. 9023, paragraph bridging columns 1-2). See also Massague, who reviews other members of the TGF-β family (1987, Cell 49:437-8, esp. p. 438, column 1, second full paragraph to the end). Similarly, PTH and PTHrP are two structurally closely related proteins which can have opposite effects on bone resorption (Pilbeam et al., 1993, Bone 14:717-720; see p. 717, second paragraph of Introduction). Finally, Kopchick et al. (U.S. Patent 5,350,836) discloses several antagonists of vertebrate growth hormone that differ from naturally occurring growth hormone by a single amino acid (column 2, lines 37-48).

Additionally, according to MPEP 2107, in order for Applicant to rebut the rejection for lack of utility imposed because the invention lacks an asserted specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, Applicant must provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing. In the instant case, even if the receptor 2B6 (Hs6m1-32) polypeptide (P58173) is found to function as an olfactory receptor, the date of publication of the sequence is October 2001, which is after the filing date of the instant application. In order for an asserted utility to be well-established, it must be well-established at the time of filing. Since the olfactory receptor 2B6 polypeptide is a post-filing reference, the asserted utility was not well-established at the time of filing.

Further according to MPEP 2107, the examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention. In the instant case, at the time of filing the instant nucleic acids were not disclosed as encoding specifically olfactory receptors, but only described as encoding generically as G protein coupled receptors (see specification pg 2, lines 5-15). G protein coupled receptors include a wide range of biologically active receptors. The fact that the specification only describes the encoded polypeptide as a G protein coupled receptor demonstrates that at the time of filing, Applicant did not know the type of receptor, if any, the encoded polypeptide would make. Since the originally disclosed properties of the claimed invention are only set forth as encoding a G protein coupled receptor, there is not a probative relationship between the

submitted evidence of the encoded polypeptide allegedly functioning as an olfactory receptor, and the disclosed properties of the encoded polypeptide being a G protein coupled receptor.

However, as noted above, the annotation of the P58173 polypeptide sequence as an olfactory receptor was published post-filing, and thus the utility was not well-established at the time of filing, and furthermore, there is not a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention, since the encoded polypeptide was only described as a G protein coupled receptor, not an olfactory receptor. In addition, it is not clear that the P58173 polypeptide was ever demonstrated to be an olfactory receptor. Thus, while Applicant is relying on P58173 (olfactory receptor 2B6) to show the utility of the claimed encoding polynucleotide, it is not clear that the function of P58173 (olfactory receptor 2B6) is actually known.

(iii) Applicant asserts that the recognition of odorants by G protein olfactory receptors is the first stage in odor discrimination (Krautwurst et al. Cell 95(7): 917-926). Applicant states that agonists and antagonists directed at this novel human G protein-coupled receptor would be expected to effect feeding behavior and potentially address, obesity, anorexia or cachexia and other feeding disorders.

Applicant's arguments have been considered but are not found to be persuasive. Applicant has not provided evidence to indicate that the claimed polynucleotide or the protein encoded by the polynucleotide is an olfactory receptor and is involved in feeding behavior, obesity, anorexia or cachexia or other feeding disorders. Additionally, nothing is disclosed in the instant specification about how the polypeptide or a specific function of the polypeptide is

affected by the agonists and antagonists. The specification discloses nothing specific or substantial for the agonists and antagonists recited in the method. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

(iv) Applicant argues that the Ji et al. article (B Biol Chem 273: 17299-17302, 1998) cited by the Examiner suggests that activities of members of a G protein-coupled receptor within a subfamily are similar. Applicant contends that the fact that there is little or no homology between subfamilies is irrelevant.

Applicant's arguments have been considered but are not found to be persuasive. The Examiner cited the Ji et al reference to indicate the state of the art at the time the invention was made. Specifically, that G protein-coupled receptors (GPCRs) and signaling molecules are extremely diverse (see for example the first 4 paragraphs at pg 17299), and each new GPCR/signaling molecule needs to be evaluated empirically to determine the precise role(s) it plays. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification of the instant application does not teach the skilled artisan which domains of the NGPCR polynucleotide and polypeptide are structurally characteristic of G protein-coupled receptors. One skilled in the art would not know the utility and function of NGPCR (SEQ ID NO: 2), even if it was a putative G protein coupled receptor because, as discussed in the related art above, G protein coupled receptors include a wide range of biologically active receptors, and neither the prior art nor the specification provides for the physiological significance of the disclosed and claimed receptor.

Ji et al. clearly states that "an increasing number of G protein coupled receptor subfamilies show diverse modes of ligand binding, signal generation, transmembrane signal transduction, and signal transfer to various cytoplasmic signal molecules other than G protein" (pg 17302, pp 4). Therefore, since the specification does not disclose any methods or working examples that demonstrate the NGPCR polynucleotide and polypeptide of the instant application exhibit similar activities of other G-protein coupled receptors, particularly olfactory receptors, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application as a G-protein coupled receptor.

The art also teaches that it is impossible to predict precisely the functions of protein molecules solely base upon sequence analysis, in view of the diversity of structure and functions of GPCRs (Bork and Eugene V. Koonin, *Nature Genetics* 18:313-318,1998). There were nearly 2000 GPCRs up to 1998 and they are classified into over 100 subfamilies according to sequence homology, ligand structure, and receptor function (Ji et al., pg 17299). Furthermore, there is no single well-established utility for the GPCR family due to the great diversity in structures and functions of the GPCR family. Even for a subfamily of the GPCR, the structure and biological activities may vary broadly. The functions of a GPCR has to be determined experimentally. Therefore, even the sequence analysis can place a GPCR into the GPCR family; such an assignment does not render a specific biological function and thus a well-established utility to the GPCR, as is the case here.

(v) Applicant submits that has been long established that there is no statutory requirement for the disclosure of a specific example. It is noted that Applicant cites *in re Gay*, 135 USPQ 311

(C.C.P.A. 1962). Applicant indicates that it is not a requirement to provide guidance as to where the important structural elements of the protein encoded by the sequences of the present that are essential to its function are located. Applicant cites *Micro Motion, Inc. V. Exac Corp.*, 16 USPQ2d 1001, 1013 (Cal. 1990).

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, the polynucleotide and polypeptide of the instant application (SEQ ID NOs: 1 and 2, respectively) are not supported by either a credible, specific and substantial ("real-world") asserted utility or a well established utility. The polynucleotide and polypeptide do not have a substantial utility because basic research is required to study the properties and activity of the claimed polynucleotide that encodes the polypeptide of SEQ ID NO: 2. The specification of the instant application does not disclose the function of the polynucleotide and polypeptide and only recites prophetic examples of how the claimed polynucleotide and polypeptide can be utilized in various assays (pg 9-16; 27-28, 33-36). Furthermore, the fact patterns of the case cited by the Applicant and of the instant rejection are significantly different, and the court decisions are not binding with regard to the instant rejections. Although as discussed in *In re Brana*, 34 USPQ 1436 (Fed. Cir. 1995), that pharmaceutical inventions necessarily include further research and development, it is clear from the instant specification that the polypeptide described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this DNA and protein, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. As discussed in the previous Office

Action, the instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

(vi) Applicant argues that whether or not the specification taught which domains are structurally characteristic of G protein-coupled receptors, those domains are present and are an inherent property of the claimed sequences. Applicant states that similarly as the functional domains are inherent to the claimed sequences which encode them, thus so is the function of a protein inherent to the sequences which encode that protein.

Applicant's arguments have been fully considered but are not found to be persuasive. The polynucleotide and polypeptide do not have a substantial utility because basic research is required to study the properties and activity of the claimed polynucleotide that encodes the polypeptide of SEQ ID NO: 2. The specification of the instant application does not disclose the

function of the polynucleotide and polypeptide and only recites prophetic examples of how the claimed polynucleotide and polypeptide can be utilized in various assays (pg 9-16; 27-28, 33-36). Applicant asserts that the claimed polynucleotide sequence encodes a novel G protein-coupled receptor. However, since the specification does not disclose any methods or working examples that demonstrate the NGPCR polynucleotide and polypeptide of the instant application exhibit similar activities of other G-protein coupled receptors, particularly odorant receptors, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application as a G-protein coupled receptor. As mentioned previously, the specification of the instant application does not teach the skilled artisan which domains of the NGPCR polynucleotide and polypeptide are structurally characteristic of G protein-coupled receptors. One skilled in the art would not know the utility and function of NGPCR (SEQ ID NO: 2), even if it was a putative G protein coupled receptor because, as discussed in the related art above, G protein coupled receptors include a wide range of biologically active receptors, and neither the prior art nor the specification provides for the physiological significance of the disclosed and claimed receptor.

(vii) Applicant asserts that the knowledge or the exact function or role of the presently claimed sequence is not required to tract expression patterns using a DNA chip. Applicant submits that the specification describes how the sequences can be represented using a gene chip format to provide a high throughput analysis of the level of gene expression. Applicant states that DNA chips have utility, as evidence by hundreds of issued U.S. patents. Applicant argues that evidence of the real world substantial utility of the present invention is further provided by the

fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Applicant asserts that the real world substantial industrial utility of gene sequences appears to be widespread and well established. Applicant also contends that given the widespread utility of "gene chip" methods using public domain gene sequence information, there can be little doubt that the use of the presently claimed novel and medically relevant sequences would have great utility in such DNA chip applications. Finally, Applicant states that the present sequences are specific markers of the human genome and such specific markers are targets for the discovery of drugs that associated with human disease and those of skill in the art would instantly recognize that the present nucleotide sequences would be ideal, novel candidates for assessing gene expression using DNA chips.

Applicant's arguments have been fully considered but are not found to be persuasive. The specification does not teach the skilled artisan any diseases or conditions associated with a mutated, deleted, translocated, upregulated, or downregulated gene of the instant application (SEQ ID NO: 1). Significant further experimentation would be required of one skill in the art to identify such a disease or condition. Furthermore, whereas a scale or a microarray or a gas chromatograph has patentable utility as a research tool, the objects being evaluated with those research tools do not necessarily have patentable utility. In the instant case, the claimed polynucleotide is not disclosed as having a specific activity, or having any property (such as a differential pattern of expression in diseased tissue) that can be specifically useful. The claimed invention is, in fact, the object of further study, merely inviting further research. Moreover, use of the claimed polypeptide in an array for screening purposes is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and

says nothing with regard to each individual member of the array. Again, this is a utility which would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of Applicant's individual polynucleotide is affected by, for example, a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed polynucleotide has no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information regarding this polynucleotide could be put.

Additionally, commercial success requires more than the mere sale of a compound. Commercial success of genomic data is not necessarily evidence of patentable utility. Commercial success is discussed in the MPEP at 716.03 and appears to be applicable to obviousness rejections, but does not appear to be a valid consideration for utility which requires specific, substantial and credible utility. Appellant also has not established a nexus between the *claimed* invention and evidence of commercial success. Appellant's argument is also not persuasive because sale of a compound is not evidence of commercial success and sale of a compound for use as a scientific tool does not appear to be a specific, substantial and credible utility as set forth in the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS".

(viii) Applicant asserts that the present nucleotide sequence has a specific utility in determining genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions. Applicant states that the full length sequences have utility in localizing the

specific of the human chromosome 6 and identification of functionally active intron/exon splice junctions. Applicant cites Venter et al. (Science 291: 1304) to allegedly demonstrate the significance of expressed sequence information in the structural analysis of genomic data.

Applicant's arguments have been fully considered but are not found to be persuasive. Although Applicant's asserts that the claimed polynucleotide has a utility in determining genomic structure of the corresponding chromosome, this assertion is credible, but not specific or substantial. Such assays can be performed with any polynucleotide. The specification does not disclose a specific DNA target or a specific chromosome that contains the claimed polynucleotide. Furthermore, the claimed polynucleotide is not linked to any disease locus. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Additionally, such a utility is considered a research utility only designed to identify a particular function of the claimed sequences and is not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." While the Examiner agrees with the Applicant on the scientific value of the claimed polynucleotide sequences and on the significance of expressed sequence information in structural analysis of genomic data, such a use of the polynucleotide sequences in gene mapping does not represent a specific and substantial utility. The exhibit and the publication cited by the Applicant merely show that the significance of expressed sequences in the structural analysis of genomic data; they do not show that the present polynucleotide sequences have a patentable utility.

(ix) Applicant contends that the invention in the instant application is akin to the patenting of tires and golf balls. Applicant submits that the present sequence is indeed like others in that it is a sequence (as new golf balls are like previous golf balls, both are golf balls and can be used in the game of golf) it is also unique, in that there are features of the claimed sequences that are not shared by other sequences (as is the case with the high flying golf ball).

Applicant's arguments have been fully considered but are not found to be persuasive. It is further noted that the patents on batteries, automobile tires, golf balls, and treatments for a variety of human diseases are issued by the USPTO because the invention in each patent has a specific and substantial utility, not simply because the claimed subject matter is related to batteries, automobile tires, golf balls, or disease treatment. For example, a golf ball has a specific feature that makes the ball fly higher and further away as compared with other golf balls; a compound has a particular property that can be used to treat a specific disease, e.g., prostate cancer. It is not the case here. The specification and Applicant's arguments do not disclose the features of the claimed sequences that are not shared by other sequences. The instant application has provided a description of an isolated nucleic acid molecule encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this nucleic acid molecule and protein or their significance. There is little doubt that, after complete characterization, this DNA and protein, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

(x) Applicant indicates that in the present case, the new Utility Guidelines result in disparate treatment to the point that they suggest a change in the law. Applicant contends that the instant

invention is more enabled and retains at least as much utility as the inventions described in the claims of the U.S. patents of record.

Applicant's arguments have been fully considered but are not found to be persuasive. It is noted that Applicant challenges the legality of the Patent Examination Utility Guidelines. Since an Examiner has no authority to comment on the legality of the Guidelines, this issue must be reserved for ruling by the Board of Patent Appeals and Interferences. The current rejection is in compliance with the most currently-published version of the Utility Guidelines which require that all biological inventions must have credible, specific and substantial ("real world") utility. Additionally, each Patent Application is examined on its own merits. The invention that was deemed allowable in one patent has no bearing on this application.

2. Claims 3-9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth at pg 11 of the Office Action of 23 October 2002 and the Office Action of 13 March 2002.

Please see arguments above.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

BEB
Art Unit
05 November 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER